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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/088,569 | 08/13/2002 | Robert C. Brunham | 1038-1226 MIS:jb | 4846 |

24223 7590 10/27/2005

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| EXAMINER | |
|---|---|
| HAMA, JOANNE | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1632 | |

DATE MAILED: 10/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/088,569 | BRUNHAM, ROBERT C. | |
| | Examiner | Art Unit | |
| | Joanne Hama, Ph.D. | 1632 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *25 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *12-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Applicant filed a response to the First Actions on the Merits, July 25, 2005.

Claims 1-11 are cancelled.

Claims 12-23 are pending.

### ***Withdrawn Rejections/Objections***

***IDS***

The Examiner acknowledges the Applicant's response, page 6, filed July 25, 2005, that the listing of references was not intended to replace an IDS.

***Abstract***

Applicant's arguments, see page 6, filed July 25, 2005, with respect to an objection that the abstract was not filed on a separate sheet of paper has been fully considered and are persuasive. Applicant has filed an abstract on a separate sheet of paper. The objection of the abstract has been withdrawn.

***Specification***

Applicant's arguments, see page 6, filed July 25, 2005, with respect to an objection to the specification regarding sequence compliance have been fully considered and are persuasive. The objection of the specification has been withdrawn.

***35 U.S.C. § 103(a)***

Applicant's arguments, see pages 8-10, filed July 25, 2005, with respect to claims 12-21 have been fully considered and are persuasive. The Applicant points out that the claims are directed to a method of using a gene encoding STK and not STK itself (Applicant's response, page 8, 5th parag.). None of the references cited by the Examiner teaches the use of a DNA vector introduced to a host. The rejection of claims 12-21 has been withdrawn.

## ***New Rejections***

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-23 are newly rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

a method of producing an immune response to the protein encoded by SEQ ID NO. 1, comprising administration to a host mammal intranasally and intramuscularly a pcDNA3 plasmid construct comprising SEQ ID NO. 1 operably linked to at least one control sequence that directs expression of a protein encoded by SEQ ID NO. 1, wherein the host mammal produces an immune response to the protein encoded by SEQ ID NO. 1,

a method of producing a vaccine for protection of a mouse against disease caused by infection with Chlamydia trachomatis MoPN EB, comprising administering a

pcDNA3 plasmid construct comprising SEQ ID NO. 1 operably linked to at least one control sequence that directs expression of a protein encoded by SEQ ID NO. 1 in a mouse, wherein said plasmid construct is administered intramuscularly and intranasally at 0, 2, and 4 weeks, and wherein following intranasal challenge of C. trachomatis MoPn EB, the mouse exhibits a reduction of C. trachomatis MoPn titer in the lungs,

and

a vaccine for a mouse for protection of a mouse against a disease caused by infection with Chlamydia trachomatis MoPn EB,

does not reasonably provide enablement for

a method of using any gene encoding any serine threonine kinase (STK) from any strain or species of Chlamydia or any fragment of STK from any strain or species of Chlamydia, other than SEQ ID NO. 1, that generates a STK-specific immune response, to produce any immune response in any host which comprises:

isolating said gene,

operatively linking said gene to at least one control sequence to produce any non-replicating vector, said control sequence directing expression of said STK or fragment there of when introduced into any host to produce any immune response to said STK or fragment thereof, and

introducing by any route, said vector into a host,

a method of producing a vaccine for protection of any host, other than mouse, against disease caused by infection with any strain of Chlamydia, which comprises:

isolating a nucleotide sequence encoding any serine-threonine kinase (STK) of any strain of Chlamydia or a fragment of said STK that generates a STK-specific immune response,

operatively linking said nucleotide sequence to at least one control sequence to produce any non-replicating vector, the control sequence directing expression of said STK or fragment thereof when introduced to any host, other than mouse, to produce any immune response to said STK or any fragment thereof, and

formulating said vector as a vaccine for in vivo administration to any host, other than mouse,

and

a vaccine for protection of any host, other than mouse, against disease cause by infection with any strain of Chlamydia.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single,

simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

The claimed invention is drawn to a method of using a gene encoding a serine-threonine kinase (STK) from a strain of Chlamydia, or a fragment of said STK that generates a STK-specific immune response. The claimed invention is also drawn to a method of producing a vaccine for protection of a host against a disease caused by infection with a strain of Chalmydia, wherein a nucleotide sequence encoding STK of a strain of Chlamydia or a fragment of said STK is used to generate a STK-specific immune response in a host. The claimed invention is also drawn to a vaccine produced by the method of making a vaccine against a disease caused by infection with a strain of Chlamydia.

The specification as filed teaches a pcDNA3 vector comprising SEQ ID NO. 1 operably linked to a human CMV major intermediate early promoter enhancer region. The specification teaches that when said pcDNA3 vector is administered to mice intranasally and intramuscularly, it protects them against C. trachomatis MoPn EB infection. However, the instantly presented claims encompass any and all STK from

any and all strains and species of Chlamydia wherein said Chlamydia strains produce lung infection. The specification as filed is not enabling for the claimed invention commensurate with the scope of the claims because the specification fails to provide sufficient guidance as to how an artisan of skill would have made and used the claimed invention without undue experimentation.

When the sequence of SEQ ID NO. 1 was compared to other sequences in the database, it shows that there is a 100% sequence identity with nt 96-1562 of the genomic sequence of Chlamyida trachomatis MoPn reported by Read et al. 2000, Nucleic Acid Research 28: 1397-1406 (a publication wherein the inventor is a co-author) and that there is an open reading frame which has an STK motif (Read, page 1405, col. 1, 3rd parag.; see also printout of sequence search, us-10-088-569.rge, page 3, result 3). Table 2 of Read et al. lists highly conserved proteins in the genome. However, the putative STK (MoPn TC0044) is not listed in the table. This indicates that the claimed sequence, SEQ ID NO. 1, while encoding a protein that has STK motifs, has no evidence of record that the encoded protein is an STK or has conserved STK activity. This issue is important because the claims, as written encompass the use of any STK from any species or strain of Chlamydia. Because the art at the time of filing does not provide any guidance as to what biological characteristics the protein encoded by SEQ ID NO. 1 has, an artisan cannot then obtain other STKs from other species and strains of Chlamydia that show these same characteristics and activities. In addition to this issue, Read et al. teach that there are significant differences between the genomes of different strains and species of Chlamydia. In table 1, Read et al. compare genomes of

Chlamydia trachomatis and Chlamydia pneumoniae and show that there is a large difference in the ORFs of the two species of Chlamydia and that there is a large difference in the ORFs of the two strains of C. trachomatis. While C. trachomatis MoPn has 894 ORFs, and C. trachomatis serovar D has 924 ORFs, C. pneumoniae has 1052 ORFs. These results indicate a significant difference between the genome and the ORFs encoding proteins between species and strains of Chlamydia. In addition to this issue, the art shows that there are great differences in sequence of STK between species of Chlamydia. SEQ ID NO. 1 showed only a 69.6% sequence match with the genomic sequence of another Chlamydia trachomatis serovor (see printout of sequence search, us-10-088-569.rge, page 6, with Accession No. AE001337, nt. 9022-10461 (note that these nucleotide base numbers comprise the sequence to a S/T protein kinase, see page 7, 2nd col. bottom of page); Stephens RS et al. 1998, Science, 282 : 754-759). Having only 69.6% sequence similarity at the nucleotide level indicates that the two sequences vary considerably and there is no teaching in the specification as to how this sequence difference between different strains of Chlamydia (as taught by Read et al. and Stephens et al.) would affect the activity of the encoded protein and whether there would be protection against Chlamydia if a mouse was immunized with the sequence of Stephens et al. In other words, there is such a large variation between the sequences of different Chlamydia that encode the putative protein kinase, an artisan would not have known whether the putative kinase from any and all Chlamydia strains and species would have a similar function. Further, because of this difference, an artisan cannot reasonably predict that being immunized for one STK from one species

of Chlamydia would necessarily ensure that immunization would occur for all species of STK from all species and strains of Chlamydia. The specification does not disclose the amino acid sequence encoded by SEQ ID NO. 1, therefore, an artisan would not know as to how closely or distantly related, the protein encoded by SEQ ID NO. 1 is to the protein encoded by the putative serine threonine kinase taught by Stephens et al. or any other putative STK from Chlamydia. Because of these differences in the genome and sequences between STKs from different species of Chlamydia and because neither the art nor the specification at the time of filing teach what characteristics comprise Chlamydial STK, an artisan does not know how to obtain any STK from any species or strains of Chlamydia.

Thus, at the time of the invention, neither the prior art nor the specification taught how to make and use a serine threonine kinase from Chlamydia. Further, a significant variation existed between the nucleotide sequences of different strains and species of Chlamydia that might have encoded a putative protein with motifs similar to serine threonine kinases of eukaryotes and the specification does not teach as to how such an variation in the protein sequence will affect the activity and function of the Chlamydial serine threonine kinase. Therefore, an artisan would have required extensive experimentation of trial and error to isolate serine threonine kinses from any and all the Chlamydia strains, develop an enzyme assay to determine if they have a kinase activity, determine the substrate required for the assay, and determined whether immunization with the isolated putative serine threonine kinases would have provided protection against infection by any Chlamydia that is infectious in the lung.

With regards to the claimed invention encompassing a "fragment" of STK, the intended use of "fragment" is considered. The claimed invention is drawn to a method of making a vaccine to a strain of Chlamydia, wherein a fragment of STK protein generates a STK-specific immune response. In order for a vaccine to have protective effects, the selected antigen must be one which the immune system will recognize upon challenge by the pathogenic host. This thus means that the "fragment" of STK cannot be any random stretch of amino acids comprised in the sequence of Chlamydial STK protein, but must be a stretch of amino acids that folds into a structure in which the immune system will interact and mount an immune response. At the time of filing, neither the specification nor the art provide any teachings as to what regions of STK result in structures which can be used to generate an immune response to Chlamydial STK. Because no guidance was provided as to what these structures are, the claims, while enabled for the protein encoded by SEQ ID NO. 1, are not enabled for any protein fragments of Clamydial STK.

With regards to the claimed invention being drawn to a method of producing a vaccine for protection of any animal host against disease caused by infection with a strain of Chlamydia using STK protein or fragment of STK protein to induce the immune response, the specification does not enable an artisan for the full breadth of any animal host. The specification teaches that Balb/c mice were intramuscularly and intranasally immunized with plasmid DNA (i.e. pcDNA3 comprising SEQ ID NO. 1), at 0, 2, and 4 weeks. Mice were then challenged intranasally with C. trachomatis MoPn EB 14 days after the last immunization. The specification teaches that mice immunized with STK

DNA had a lung titer ($log_{10}$ IFU) of 31.6, which is 316.2 fold lower than the negative control group (specification, page 12, and Figure 1B). While the specification provides these teachings, the specification does not teach other animal hosts immunized with pcDNA3 comprising SEQ ID NO. 1 that exhibited reduced Chlamydia trachomatis MoPn titer in the lungs. According to the Chattergoon et al. 1997, The FASEB Journal, 11: 753-763, "the ability of plasmid DNA to induce immune responses after inoculation has been demonstrated in several animals. Further, within the limits of these disease models, the immune responses elicited by DNA vaccines have been shown to be protective.... However, to date there is little evidence that the immune responses induced by these vaccines will be completely protective against any pathogen (Chattergoon et al., page 762, under Conclusion)." Further, post-filing art teaches that while efficacy of a vaccine has been demonstrate in animal trials, the efficacy is not predictable in phase I clinical trials (Ulmer, 2001, Curr. Opin. Drug Discov. Devel. 4: 192-7. see abstract; Cui, 2005, Adv. Genet. 54: 257-289, see abstract). In addition to this issue, DeMars et al. (U.S. Patent No. 6,001,372, patented December 14, 1999) teach that apart from serovar specificity issues, humans have a variety of MHC class II types, each type determining the specific antigenic groups to which an individual's immune system can respond. Thus what is antigenic for one human MHC type, may not be antigenic for others. This is particularly troubling for those seeing to develop (Chlamydia) vaccines for the human population in general (DeMars et al, col. 2, lines 40-45). Thus, while the specification teaches that immunizing mice with pcDNA3 comprising SEQ ID NO. 1 reduces Chlamydia lung titer in mice, the specification does

not teach a method of protecting against Chlamydial infection in other species of animals.

The claimed invention is broadly drawn to using any gene encoding STK or a fragment of STK from any species or strain of Chlamydia, wherein introduction of said gene results in protection of a host against any disease caused by infection with any species or strain of Chlamyida. According to the art, there are four different groups of Chlamydia to consider: Chlamydia trachomatis of the A-C serovars that are involved in trachoma, C. Trachomatis of the D-K serovars that are involved in STD syndromes, the LGV, L1, L2, L3 serovars that cause the invasive STD syndrome lymphogranuloma venereum, and C. pneumoniae, a cause of respiratory infections of varying severity (Proceedings of the Chlamydia Vaccine Development Colloquium, 4-5 June 2003, edited by Woodall, J.P., The Albert B. Savin Vaccine Institute, 1st edition, page 15, under "Magnitude of the Problem"). While the specification teaches that mice vaccinated with pcDNA3 comprising SEQ ID NO. 1 were challenged with C. trachomatis MoPn EB and demonstrated a lower titer of C.trachomatis MoPn, neither the specification nor the art teach that vaccination with pcDNA comprising SEQ ID NO. 1 could be used as a vaccine to prevent disease resulting from infection of other strains and species of Chlamydia. Further, The art teaches that four groups tried several decades ago to develop a vaccine against trachoma: a couple in the United States, Bietti in Italy and Collier in the United Kingdom. The three conclusions that have withstood the test of time, namely: the vaccines can protect, but the protection is short lived, protection is for the most part serovar specific, and hypersensitization is longer

lasting than protection (Proceedings of the Chlamydia Vaccine Development Colloquium, 4-5 June 2003, edited by Woodall, J.P., The Albert B. Savin Vaccine Institute, 1st edition, page 56 under "C. Trachomatis"). With regards to the claimed invention being drawn to protecting a host from multiple species and strains of Chalmydia, post-filing art teaches that there is no known vaccine that can protect a host against multiple strains and species of Chlamydia. No guidance was provided for the full breadth of the claimed invention.

The claimed invention broadly encompasses the use of any non-replicating vector. In addition to encompassing plasmids, non-replication vectors also include viral vectors. Post-filing art teaches that viral vectors are unpredictable. For example, lentiviral vectors integrate in the host chromosome non-specifically. The result of this is that near the site of integration, transcriptional elements such as repressors can turn off transcription of the DNA construct (Somia and Verma, 2000, Nature Reviews: Genetics, 1: 91-99, page 93, 2nd col., 1st parag.). In the case of adenoviral vectors, one challenge of using adenoviral vectors is that humoral immunity precludes the repeat administration of the vector because the subsequent antibody response will be boosted by memory cells (Somia and Verma, page 95, 1st col., 1st parag.). With regards to the instant invention, the specification teaches that pcDNA3 comprising SEQ ID NO.1 was administered three times (specification, Example 2). In addition to this, the specification teaches that booster doses are encompassed by the claimed invention (specification, page 7, lines 27-28). However, with regards to the art teaching that adenoviral vectors are destroyed by the immune response of the host following subsequent administration,

nothing in the specification teaches an artisan how to overcome this issue of enablement. Thus, the claimed invention is limited to pcDNA3.

The claimed invention broadly encompasses any route of delivery for the DNA construct. The specification teaches that administration parenterally, subcutaneously, intravenously, intradermally, or intramuscularly are contemplated (specification, page 7, lines 7-8). At the time of filing, the art teaches that systemic administration of DNA constructs has proven to be difficult because of the rapid clearance of DNA from the circulation and the generally poor levels of expression following this method (Minchin et al., 2001, J. of Pharm. and Exp. Therap., 296: 1006-1012, see page 1006, 1st col., 1st parag.). While the working example teaches intranasally and intramuscularly, the specification does not teach other routes of administration of pcDNA3 comprising SEQ ID NO.1 wherein an immune response is elicited and reduces Chlamydial titer in mouse lungs. Thus, the claimed invention is not enabled for the full breadth of any route of administration.

In view of the lack of guidance, working examples, breadth of the claims, and state of the art at the time of the claimed invention was made, it would have required undue experimentation to make and/or use the invention as claimed.

***Response to Arguments***

Applicant's arguments, see pages 6-7, filed July 25, 2005, with respect to claims 12-23 have been fully considered and are persuasive if the claims are amended. The Applicant points out that claim 12 and its dependent claims are drawn only to producing

an immune response in a host. The claims are not drawn to a protective immune response. Therefore, claims 12-21 are only to be read that the use of pcDNA3 vector comprising a nucleic acid sequence encoding SEQ ID NO. 1, wherein said vector is used in a method to generate antibody. In order to distinguish that claims 12-21, when read in light of the specification, do not encompass the intended use of using the plasmid vector comprising SEQ ID NO. 1 for inducing a protective response, claims should be amended to exclude the intended use. That is, the claims should be read such that the plasmid vector comprising SEQ ID NO. 1 is used to for the purpose of generating antibody. However, the argument does not overcome the fact that claims 22 and 23 required that there is a protective immune response.

Claims 12-23 are newly rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The final Written Description Examination guidelines that were published on January 5, 2001 (66 FR 1099; available at http://www.uspto.gov/web/menu/current.html#register).

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" Vas-Cath Inc. v.

Mahurkar, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1116.

While the specification and the art provide adequate written description for the isolated nucleic acid sequence designated by SEQ ID NO. 1, the specification fails to adequately describe other serine-threonine kinases (STKs) obtained from any strain of Chlamydia or any fragments of STK such that an immune response would be generated. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). In the instant case, the Applicant has taught a plasmid vector, pcDNA3, comprising SEQ ID NO. 1. While the specification teaches that SEQ ID NO. 1 encodes a putative serine-threonine kinase, neither the art nor the specification teach that the protein encoded by SEQ ID NO. 1 functions as a serine-threonine kinase, like that of eukaryotic cells. It thus follows that because it is unclear whether the putative STK encoded by SEQ ID NO. 1 functions as a STK, it is unclear how an artisan would identify other nucleic acids encoding STKs from other strains of Chlamydia. While the art teaches in great detail the many

parameters one can change in hybridization conditions to obtain a nucleic acid sequence by altering the temperature, salt concentrations, time of incubation, length of nucleic acid and composition of the nucleic acid composition, the specification fails to describe the relevant identifying characteristics of STKs from Chlamydia such that an artisan would know how to identify one. In addition to this issue, the claims broadly encompass any fragment of STK obtained from Chlamydia. However, because the protein encoded by SEQ ID NO. 1 is a putative serine-threonine kinase, it is unclear as to what characteristics of the protein encoded by SEQ ID NO. 1 an artisan would use to identify other STK proteins in other species and strains of Chlamydia. With regards to the claims encompassing any fragment of STK from Chlamydia that generates an STK-specific immune response, nothing in the specification or the art provide any guidance as to what structures of STK are necessary for generating an STK-specific immune response, such that the immune response protects the host from pathogen challenge. The skilled artisan cannot envision all the characteristics that comprise Chlamydia STK proteins nor can an artisan envision all fragments of Chlamydia STK proteins that can be used to invoke a protective immunological response of a host against Chlamydia, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method used. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only SEQ ID NO. 1 meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

***Conclusion***

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

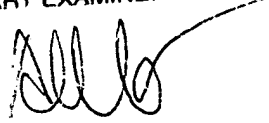
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JH

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER



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Qy        661 ACTCAAGCATTGCAACCAGACCCAGAAGCACGGTTTCCTTCTATGCAAGAGTTTGCTACG 720

Db        661 ACTCAAGCATTGCAACCAGACCCAGAAGCACGGTTTCCTTCTATGCAAGAGTTTGCTACG 720

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Db        841 ATGCCGGAAGGGATGGCTCTGCACATTTATTCACAAAAAGAGCCCTGTGATTTACATAAT 900

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Qy       1021 GCGCAAGATATCCCAACAGTAATAAAAACATTGGATACTCTTTGTAAAACAATGCATATT 1080

Db       1021 GCGCAAGATATCCCAACAGTAATAAAAACATTGGATACTCTTTGTAAAACAATGCATATT 1080

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Db       1081 CCGCTTTGTGAAAAAGGGATTTCCTGCTGCTGTTTTATATTTTTCCAACAAGAACTCATG 1140

Qy       1141 TGCTTTTCTTGTGGGAAAACTGATTTCTCGTTAAAAAAGCAAACGAGGGGAGTGCAACGT 1200

Db       1141 TGCTTTTCTTGTGGGAAAACTGATTTCTCGTTAAAAAAGCAAACGAGGGGAGTGCAACGT 1200

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Db       1321 TATTTATACTGTCCTTCTTTCCTGAAGTTGCAAGATAGAGGGCAAATGGATATATTCTGC 1380

Qy       1381 CAAACAGATTACCTTCAGAAGGAAGTGAGGCAGAAGTATGACGGAAGTCTTTATCCTTCA 1440

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Db       1441 ACACTTATCAGCTTAAAAAGAGTCCGG 1467


RESULT 3
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LOCUS       AE002272               11357 bp    DNA     linear   BCT 26-MAR-2003
DEFINITION  Chlamydia muridarum section 4 of 85 of the complete genome.
ACCESSION   AE002272 AE002160
VERSION     AE002272.2  GI:8163112
KEYWORDS    .
SOURCE      Chlamydia muridarum
. ORGANISM  Chlamydia muridarum
            Bacteria; Chlamydiae; Chlamydiales; Chlamydiaceae; Chlamydia.
REFERENCE   1  (bases 1 to 11357)
  AUTHORS   Read,T., Brunham,R., Shen,C., Gill,S., Heidelberg,J., White,O.,
            Hickey,E., Peterson,J., Utterback,T., Berry,K., Bass,S., Linher,K.,
            Weidman,J., Khouri,H., Craven,B., Bowman,C., Dodson,R., Gwinn,M.,
            Nelson,W., DeBoy,R., Kolonay,J., McClarty,G., Salzberg,S., Eisen,J.
            and Fraser,C.
  TITLE     Genome sequences of Chlamydia trachomatis MoPn and Chlamydia
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  JOURNAL   Nucleic Acids Res. 28 (6), 1397-1406 (2000)
  MEDLINE   20150255
   PUBMED   10684935
REFERENCE   2  (bases 1 to 11357)
  AUTHORS   Read,T., Brunham,R., Shen,C., Gill,S., Heidelberg,J., White,O.,
            Hickey,E., Peterson,J., Utterback,T., Berry,K., Bass,S., Linher,K.,
            Weidman,J., Khouri,H., Craven,B., Bowman,C., Dodson,R., Gwinn,M.,
            Nelson,W., DeBoy,R., Kolonay,J., McClarty,G., Salzberg,S., Eisen,J.
            and Fraser,C.
  TITLE     Direct Submission
  JOURNAL   Submitted (01-MAR-2000) The Institute for Genomic Research, 9712
            Medical Center Dr, Rockville, MD 20850, USA
COMMENT     On Jun 1, 2000 this sequence version replaced gi:7190083.
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Query Match           100.0%;  Score 1467;  DB 1;  Length 11357;
Best Local Similarity  100.0%;  Pred. No. 0;
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Db         96 ATGCTTGAATTAGGCGTATCGTTTCCTTCCAAGACTAAATATCTTCTGACACGAGAACTT 155

Qy         61 AGTCGTAAGGTAGGCTTGACTGTCTATCAAGGAGTGGATGAGAGTTCTTCTCGTCCTGTG 120
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Db        216 GTGATCAAAGCATTGGTATCTCCAGGGATTCATGACCAGCGTTTTCTTCGTGCTTTTGAA 275

Qy        181 GAAGAAGCTAGGATTATGCAACTTGTAGATCATCCGGCATTTGTTCGATTAGAAGAAAAA 240
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Db        276 GAAGAAGCTAGGATTATGCAACTTGTAGATCATCCGGCATTTGTTCGATTAGAAGAAAAA 335

Qy        241 GGTGAGTGGGAGCAAGGACGTTATTTCGTTTCTGAATATATTTTAGGGCATTCATTGCGA 300
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Qy        301 GATATTATCCTTTCATCTCATCTCGCTTTGGATAAGGCAGTTTCTATTGTTTTACAAGTA 360
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Db        396 GATATTATCCTTTCATCTCATCTCGCTTTGGATAAGGCAGTTTCTATTGTTTTACAAGTA 455

Qy        361 GCGCAGGCAATAACGGCTCTTCATAAACATCATGTTTTACATCTCGATATTAAACCTGAA 420

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Qy        421 AACATCATGATTTCTCGGTTGGGAGAGGTCAAGTTGATCGATTATGGGCTTTCAGCCTGG 480

Db        516 AACATCATGATTTCTCGGTTGGGAGAGGTCAAGTTGATCGATTATGGGCTTTCAGCCTGG 575

Qy        481 CAATTTAATCATTGGGGTTCGCCTGCATATATGAGTCCCGAACAGAGCAGGCAGGAAAAG 540

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Db       1236 TGCTTTTCTTGTGGGAAAACTGATTTCTCGTTAAAAAAGCAAACGAGGGGAGTGCAACGT 1295

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Db       1536 ACACTTATCAGCTTAAAAAGAGTCCGG 1562
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RESULT 4
AY148437

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LOCUS       AY148437               1473 bp    DNA     linear   BCT 23-SEP-2003
DEFINITION  Chlamydia trachomatis serovar L2 serine/threonine kinase Pkn5 gene,
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ACCESSION   AY148437
VERSION     AY148437.1  GI:27465035
KEYWORDS    .
SOURCE      Chlamydia trachomatis
  ORGANISM  Chlamydia trachomatis
            Bacteria; Chlamydiae; Chlamydiales; Chlamydiaceae; Chlamydia.
REFERENCE   1  (bases 1 to 1473)
  AUTHORS   Verma,A. and Maurelli,A.T.
  TITLE     Identification of Two Eukaryote-Like Serine/Threonine Kinases
            Encoded by Chlamydia trachomatis Serovar L2 and Characterization of
            Interacting Partners of Pkn1
  JOURNAL   Infect. Immun. 71 (10), 5772-5784 (2003)
  MEDLINE   22862889
   PUBMED   14500499
REFERENCE   2  (bases 1 to 1473)
  AUTHORS   Verma,A. and Maurelli,A.T.
  TITLE     Direct Submission
  JOURNAL   Submitted (05-SEP-2002) Microbiology, Uniformed Services University
            Health Sciences, 4301, Jones Bridge Road, Bethesda, MD 20814, USA
FEATURES             Location/Qualifiers
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ORIGIN
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  Matches 1179;  Conservative    0;  Mismatches  263;  Indels    0;  Gaps    0;

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Qy         86 ATCAAGGAGTGGATGAGAGTTCTTCTCGTCCTGTGGTGATCAAAGCATTGGTATCTCCAG 145

Db         89 ATCAAGGTGTGGATGAGCACTCTTCTCGTCCTGTTGTTATTAAAACATTGGTATCGCCAG 148

Qy        146 GGATTCATGACCAGCGTTTTCTTCGTGCTTTTGAAGAAGAAGCTAGGATTATGCAACTTG 205

Db        149 GAATTCATGATCGACGTTTTCTTCGTGCTTTCGAAGAAGAAGCAAGGATTATGCAGCTAG 208

Qy        206 TAGATCATCCGGCATTTGTTCGATTAGAAGAAAAAGGTGAGTGGGAGCAAGGACGTTATT 265

Db        209 TAACGCACCCAGCGTTTGTTCGCTTGGAGGATAGAGGAGAGTGTGAGCAGGGACGCTACT 268
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Qy       326 CTTTGGATAAGGCAGTTTCTATTGTTTTACAAGTAGCGCAGGCAATAACGGCTCTTCATA 385
Db       329 CTTTGGATAAAGCGATTTCTATTGTCTTGCAAGTAGCGCAAGCTATCACGACTCTGCATC 388

Qy       386 AACATCATGTTTTACATCTCGATATTAAACCTGAAAACATCATGATTTCTCGGTTGGGAG 445
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VERSION     AE001337.1  GI:3329113
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REFERENCE   1  (bases 1 to 13324)
  AUTHORS   Stephens,R.S., Kalman,S., Lammel,C.J., Fan,J., Marathe,R.,
            Aravind,L., Mitchell,W.P., Olinger,L., Tatusov,R.L., Zhao,Q.,
            Koonin,E.V. and Davis,R.W.
  TITLE     Genome sequence of an obligate intracellular pathogen of humans:
            Chlamydia trachomatis
  JOURNAL   Science 282 (5389), 754-759 (1998)
  MEDLINE   99000809
   PUBMED   9784136
REFERENCE   2  (bases 1 to 13324)
  AUTHORS   Kalman,S., Mitchell,W., Marathe,R., Lammel,C., Fan,J., Hyman,R.W.,
            Olinger,L., Grimwood,J., Davis,R.W. and Stephens,R.S.
  TITLE     Comparative genomes of Chlamydia pneumoniae and C. trachomatis
  JOURNAL   Nat. Genet. 21 (4), 385-389 (1999)
  MEDLINE   99206606
   PUBMED   10192388
REFERENCE   3  (bases 1 to 13324)
  AUTHORS   Stephens,R.S., Kalman,S., Lammel,C.J., Fan,J., Marathe,R.,
            Aravind,L., Mitchell,W.P., Olinger,L., Tatusov,R.L., Zhao,Q.,
            Koonin,E.V. and Davis,R.W.
  TITLE     Direct Submission
  JOURNAL   Submitted (20-MAY-1998) Program in Infectious Diseases, University
            of California, 235 Warren Hall, Berkeley, CA 94720-7360, USA
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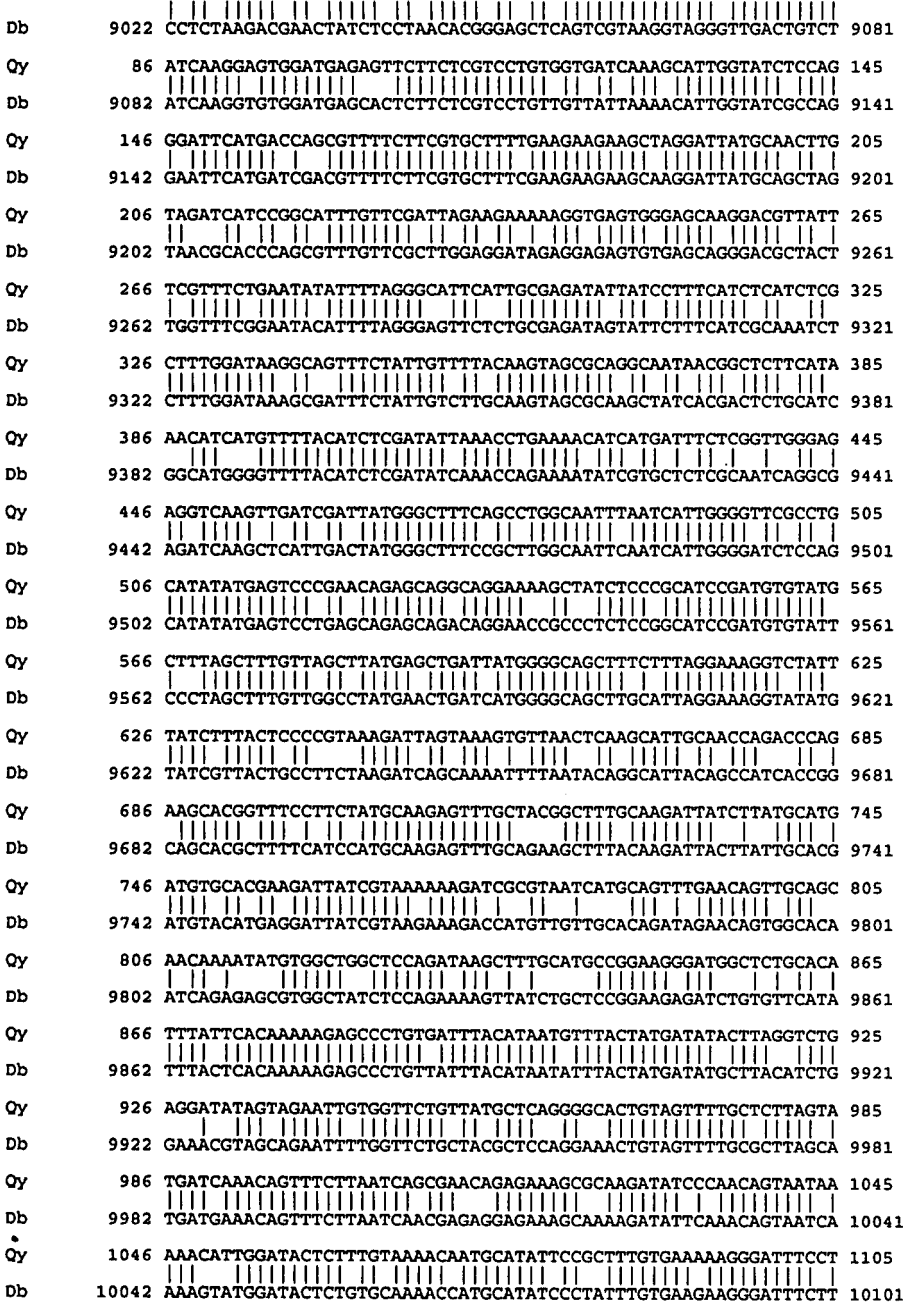

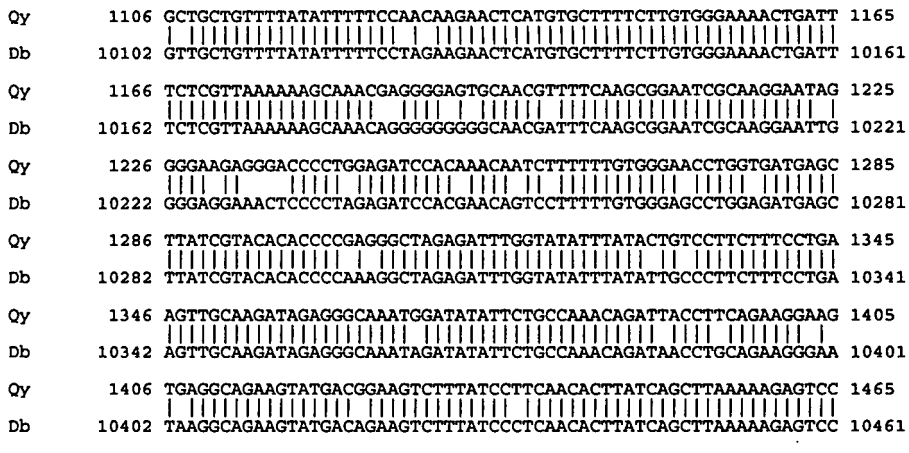

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VERSION AE016994.1 GI:29834116
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ORGANISM Chlamydophila caviae GPIC
Bacteria; Chlamydiae; Chlamydiales; Chlamydiaceae; Chlamydophila.
REFERENCE 1 (bases 1 to 304769)
AUTHORS Read,T.D., Myers,G.S., Brunham,R.C., Nelson,W.C., Paulsen,I.T., Heidelberg,J., Holtzapple,E., Khouri,H., Federova,N.B., Carty,H.A., Umayam,L.A., Haft,D.H., Peterson,J., Beanan,M.J., White,O., Salzberg,S.L., Hsia,R.C., McClarty,G., Rank,R.G., Bavoil,P.M. and Fraser,C.M.
TITLE Genome sequence of Chlamydophila caviae (Chlamydia psittaci GPIC): examining the role of niche-specific genes in the evolution of the Chlamydiaceae
JOURNAL Nucleic Acids Res. 31 (8), 2134-2147 (2003)
MEDLINE 22569155
PUBMED 12682364
REFERENCE 2 (bases 1 to 304769)
AUTHORS Read,T., Myers,G., Brunham,R., Nelson,W., Paulsen,I., Heidelberg,J., Holtzapple,E., Khouri,H., Fedorova,N., Carty,H., Umayam,L., Haft,D., Peterson,J., Beanan,M., White,O., Salzberg,S., Hsia,R.-C., McClarty,G., Rank,R., Bavoil,P. and Fraser,C.
TITLE Direct Submission
JOURNAL Submitted (29-OCT-2002) The Institute for Genomic Research, 9712 Medical Center Dr, Rockville, MD 20850, USA
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